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10/554,625

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Derek O'Hagan

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02/23/2010

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY- X100B

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/554,625 | <b>Applicant(s)</b><br>O'HAGAN ET AL. |  |
|                              | <b>Examiner</b><br>Zachariah Lucas   | <b>Art Unit</b><br>1648               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7,9-11 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7,9-11, 16-20 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 7, 9-11, and 16-27 are pending in the application.
2. In the prior action, mailed on July 24, 2009, claims 1-29 were pending in the application; with claims 21, 27, and 28 withdrawn from consideration; and claims 1-20, 22-26, and 29 under consideration and rejected.
3. In the response of December 21, 2009, the Applicant amended claims 7, 16, 21, and 22; and cancelled claims 1-6, 8, 28, and 29.
4. Claims 7, 9-11, 16-20, and 22-26 are under consideration.

### ***Claim Objections***

5. **(Prior Objection- Withdrawn)** Claims 1, 2, 6-8, 14, 15, and 22 were objected to because of the following informalities: these claims refer to Figures 2A-2C of the specification. In view of the amendment of the pending claims to refer to the relevant positions of SEQ ID NO: 2 rather than the sequence of the indicated Figures, the objection is withdrawn.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. **(Prior Rejection- Withdrawn)** Claim 29 was rejected under 35 USC 112, second paragraph as indefinite because the claim provides for the use of “use of a composition according to any of claims 1-6,” but failed to recite any active, positive steps delimiting how this use is actually practiced. In addition, the claim was also rejected under 35 U.S.C. 101 because the

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claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. In view of the cancellation of the claim from the application, the rejection is withdrawn.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **(Prior Rejection- Withdrawn)** Claims 1, 3-5, 7, 9-20, and 29 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement with respect to compositions (and methods of use thereof) comprising the administration of a HCV immunogen comprising an HCV E1E2 complex having at least 80% identity to positions 192-809 of Figure 2 (i.e. positions 20-637 of SEQ ID NO: 2) wherein the immunogen comprising that sequence would be able to induce an anti-HCV immune response. In view of the amendment of the claims to delete reference to any sequence having at least 80% identity to the sequence, and instead require the use of the sequence of residues 20-637 of SEQ ID NO: 2, the rejection is withdrawn.

10. **(Prior Rejection- Withdrawn)** Claims 7-20 and 22-26 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for the induction of an immune response against HCV through the practice of the claimed methods, does not reasonably provide enablement for methods for the therapy of HCV through such methods.

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In view of the amendment of the claim to remove the reference to the use of therapeutically effective amounts, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. **(Prior Rejections- Withdrawn)** Claims 1-11 and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Houghton et al. (WO 01/47551) and of Choo et al. (PNAS 88:2451-55). Claims 1, 3, 7, 9-11 and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (WO 96/20698) in combination with the teachings of Selby et al. (U.S. 6,121,020) and of Felgner et al. (J Biol Chem 269:2550-61) and Liu et al. (Pharm Res 13:1856-60). The pending claims have been amended to incorporate the limitations of claim 12, which was not included in the present rejection. The rejections are therefore withdrawn.

13. **(Prior Rejection- Extended as Necessitated by Amendment and Maintained)** Claims 12-20 and 22-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton and Choo as applied to claims 1-11 and 29 above, and further in view of Ertl (U.S. 6,210,663). In view of the amendment of the claims, the rejection is extended to pending claims 7 and 9-11

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(which claims have been amended to incorporate the limitations of claim 12), and withdrawn from cancelled claims 12-15.

The Applicant traverses the rejection on the basis that "none of the cited references teaches or suggests that the use of two compositions as claimed would serve to stimulate an immune response." The Applicant asserts that there is no recognition in Houghton of the primary administration of a polynucleotide followed by a secondary administration of a polypeptide would elicit an immune response; and asserts that Ertl neither pertains to HCV specifically, nor actually provides an example wherein a protein boost is administered after a primary DNA vaccination. The arguments are not found persuasive.

In each argument, the Applicant focuses on the teachings of the specific references without looking to what would have been obvious to those of ordinary skill in the art based on the prior art references as a whole. It is noted that it has been established in law that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With respect to the assertion that Ertl's examples fail to demonstrate the use of the suggested prime/boost methodology, it is noted that the provision of such examples is not required to render obvious a claimed invention so long as the teachings in the art teach or suggest the claimed limitations and provide those of ordinary skill in the art with a reasonable expectation of success in the modification of the prior art to arrive at the claimed invention. As the art suggests the general applicability of the suggested prime/boost methodology, it would have been obvious to those of ordinary skill in the art to have applied it to the induction of an

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immune response against the E1E2 antigens suggested by Houghton and Choo. Because the art suggests that the methodology would have been useful for the induction of such an immune response, and as the Applicant has provided no evidence to the contrary, the arguments are not found persuasive.

The rejection is therefore maintained over claims 7-11, 16-20, and 22-26 for the reasons above, and the reasons of record.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Double Patenting***

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. **(Prior Rejection- Maintained)** Claims 1-20, 22-26, and 29 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of U.S. Patent No. 7,329,408 in view of the teachings of Houghton, Choo, and Ertl as applied above. The rejection is withdrawn from cancelled claims 1-6, 8, 12-15, and 29. As no arguments have been presented with respect to the remaining claims, and as it is not Office policy to hold such rejections in abeyance, the rejection is maintained on the remaining claims for the reasons of record.

17. **(Prior Rejection- Maintained)** Claims 1-20, 22-26, and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-42 and 62-76 of copending Application No. 10/775964, or over claims 1-3, 5, 6, 9, 10, 12, 13, 15-17, 23, 26-28, 32-35, 37-39, 42-48, 52, 54-57, 61, 63, 64, 69, 76, 77, 79-81, 83, and 87-101 of copending application 10/757708, in view of Houghton, Choo, and Ertl as applied above. The rejection is withdrawn from cancelled claims 1-6, 8, 12-15, and 29. As no arguments have been presented with respect to the remaining claims, and as it is not Office policy to hold such rejections in abeyance, the rejection is maintained on the remaining claims for the reasons of record.

This is a provisional obviousness-type double patenting rejection.



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18. **(Prior Rejection- Maintained)** Claims 1-20, 22-26, and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 12, 13, 15-38, 41, 45-48, 51, 52, 55-71, 76, and 77 of copending Application No. 11/653792 in view of Houghton, Choo, and Ertl as applied above. The rejection is withdrawn from cancelled claims 1-6, 8, 12-15, and 29. As no arguments have been presented with respect to the remaining claims, and as it is not Office policy to hold such rejections in abeyance, the rejection is maintained on the remaining claims for the reasons of record.

This is a provisional obviousness-type double patenting rejection.

19. **(Prior Rejection- Maintained)** Claims 1-20, 22-26, and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 12/231351; or claims 117, 22-33, 36-40, and 55-62 of copending application 12/087330; in view of Houghton, Choo, and Ertl as applied above. The rejection is withdrawn from cancelled claims 1-6, 8, 12-15, and 29. As no arguments have been presented with respect to the remaining claims, and as it is not Office policy to hold such rejections in abeyance, the rejection is maintained on the remaining claims for the reasons of record.

This is a provisional obviousness-type double patenting rejection.

20. **(Prior Rejection- Maintained)** Claims 1-20, 22-26, and 29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6, 9-

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12, 15-24, 26-31, 35-44, and 46-50 of U.S. Patent No. 6,884,435; or over claims 1-13, 15-17, 20, and 24-51 of US Patent No 6,753,015; in view of Houghton, Choo, and Ertl. The rejection is withdrawn from cancelled claims 1-6, 8, 12-15, and 29. As no arguments have been presented with respect to the remaining claims, and as it is not Office policy to hold such rejections in abeyance, the rejection is maintained on the remaining claims for the reasons of record.

### ***Conclusion***

21. No claims are allowed.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/  
Primary Examiner, Art Unit 1648